UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* DAVID KESTER, Plaintiffs and Relator, -against- NOVARTIS PHARMACEUTICALS CORPORATION Defendant.	**11 CIV. 8196 (CM) (JCF)** **ORAL ARGUMENT REQUESTED**

NOVARTIS PHARMACEUTICALS CORPORATION'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION TO COMPEL DISCOVERY RESPONSES FROM THE UNITED STATES AND FROM THE STATES OF CALIFORNIA, GEORGIA, ILLINOIS, INDIANA, MARYLAND, MICHIGAN, NEW JERSEY, NEW YORK, OKLAHOMA, WASHINGTON AND WISCONSIN

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Novartis Pharmaceuticals Corporation ("NPC") submits this reply memorandum of law in further support of its motion to compel (Dkt. No. 245) and in response to the oppositions filed by the United States (Dkt. No. 280) ("U.S. Opp.") and States (Dkt. No. 273) ("States' Opp.").[1]

PRELIMINARY STATEMENT

The Government alleges in its complaints and even in opposing NPC's motion to compel that the purported kickback schemes in this case resulted in compromised patient care and corrupted clinical judgment. The discovery sought by NPC is directly relevant to whether there is any merit to these allegations, and specifically to determining whether: (i) BioScrip's efforts to contact Exjade patients were consistent with the adherence initiatives and programs the Government itself advocates; (ii) the qualifications of BioScrip's personnel and the quality of BioScrip's patient outreach were sufficiently appropriate for the Government itself to have designated BioScrip to dispense Exjade in the VA system; and (iii) the clinical information the specialty pharmacies provided to doctors regarding Myfortic (which the Government claims was "pretextual") and the clinical reasons why Exjade adherence is important (which the Government disputes) are in fact consistent with the Government's own clinical understanding. The Government's contention that this information is irrelevant ignores its own theory of the case. Moreover, the requested discovery is relevant to whether there has been any violation of the AKS and, if so, whether NPC had the requisite intent to violate the statute and whether the statutory and regulatory framework provide sufficient notice that NPC's conduct violated the statute. Unable to refute the plain relevance of the requested discovery, the Government offers only an unsupported burden objection and, in the case of the States, a flawed objection that the States lack control of the documents in the possession of their State agencies. Because the

[1] Defined terms have the meanings set forth in NPC's opening memorandum of law dated September 10, 2014 ("Br.").

requested discovery is reasonably calculated to lead to the discovery of admissible evidence, NPC's motion to compel should be granted in its entirety.

ARGUMENT

I. THE REQUESTED DISCOVERY IS RELEVANT TO MATTERS THE GOVERNMENT ITSELF CONTINUES TO PUT AT ISSUE AND MANY OTHER ASPECTS OF THE CLAIMS AND DEFENSES IN THIS CASE

The Government fails to address one of the most fundamental reasons the requested discovery is relevant: The Government itself has put at issue the matters to which the discovery NPC seeks pertains. Despite the Government's arguments in its Oppositions that the only issues in this case are whether NPC used patient referrals, rebates, or discounts to induce specialty pharmacies to recommend its medications, *see*, *e.g.*, U.S. Opp. at 1, 2, 8, States' Opp. at 1, its pleadings are not so sterile. Rather, they prominently feature allegations that BioScrip's outreach efforts to Exjade patients were inappropriately conducted and that the information about Myfortic's clinical benefits and importance of adherence to Exjade therapies that the specialty pharmacies provided to physicians and patients, respectively, was pretextual. For example, the Government now contends in its Oppositions that if NPC offered BioScrip any remuneration for its outreach efforts to Exjade patients, such remuneration is a violation of the AKS,[2] and evidence regarding the propriety of BioScrip's communications with patients and the qualifications of its employees is simply irrelevant. *See*, *e.g.*, U.S. Opp. at 2-3; States' Opp. at 1, 9-10. Yet the Government's complaints and its Oppositions are replete with allegations about shortcomings in BioScrip's adherence initiative. *See*, *e.g.*, Second Am. Compl. (Dkt. No. 231)

[2] Throughout its Oppositions, the Government implies that the Court has already resolved many issues in this case that have yet to be briefed, much less decided, including whether NPC offered remuneration to BioScrip for its outreach efforts and whether any such remuneration was improper. The Court's prior rulings were made in the context of motions to dismiss, where factual allegations—like the Government's allegations regarding improper remuneration to BioScrip—must be accepted as true.

¶ 228 (BioScrip personnel lacked clinical knowledge or patient information to provide counseling); *see also* U.S. Opp. at 7 (arguing that BioScrip's adherence efforts did not adequately address patient side effects). The requested adherence-related discovery is relevant to the issue of what the Government believes is a *proper* adherence initiative and thus relevant to the Government's allegations regarding the shortcomings in BioScrip's adherence initiative. The Government's response that its adherence efforts were "different" from those of BioScrip implicitly *concedes* the relevance of this information. *See id*. at 2. The Government cannot claim that its adherence efforts are different without allowing NPC to test that assertion by providing information about those programs.[3]

Likewise, although the Government argues that whether the specialty pharmacies' recommendations to physicians and patients were clinically appropriate is irrelevant, its complaints and Oppositions contend otherwise. *Compare*, *e.g.*, *id.* at 3 (contending that NPC's purported focus on whether the alleged kickbacks "were clinically acceptable or did not in fact influence anyone" is irrelevant) *with* States' Opp. at 1 ("This case is about how Novartis *corrupted the medical judgment of pharmacies*.") (emphasis added); *see also* Second Am. Compl. ¶ 6 ("[H]undreds, possibly thousands, of transplant patients have undergone switches in their medication as a result of recommendations from pharmacies that were based on undisclosed financial, rather than independent clinical, considerations."). Documents relating to iron

[3] The Government offers no response to that portion of NPC's motion seeking to compel discovery relating to the Government's designation of BioScrip to dispense Exjade to VA patients. The Government's refusal to provide this discovery is a poignant example of the Government's double standard of relevance: The Government alleges that BioScrip's employees were unqualified to counsel Exjade patients; yet, according to BioScrip employees, the Government designated BioScrip to dispense Exjade to VA patients. The Government should not be permitted to contend that BioScrip's employees were unqualified yet withhold as "irrelevant" evidence that would show the Government itself deemed BioScrip's employees sufficiently qualified to counsel the VA's Exjade patients.

chelation and kidney transplant immunosuppression therapies at the Government's own hospitals will show the Government's views on appropriate clinical considerations in treating iron overload and immunosuppression post transplant and are therefore relevant to the Government's allegation that the communications between the specialty pharmacies and the physicians and patients were pretextual or not clinically supported.[4]

The Government cannot have it both ways. It cannot affirmatively allege and argue that the Exjade rebates and patient allocations at issue were improper because they resulted in inappropriate medication adherence efforts while at the same time withhold discovery relevant to determining whether BioScrip's adherence initiative was meaningfully different from the very initiatives the Government itself promotes. Nor can it denounce as "pretext" the clinical recommendations of specialty pharmacies while withholding discovery that would reveal whether the Government itself has credited the same information the specialty pharmacies provided to physicians and patients. Conspicuously, nowhere in its Oppositions does the Government abandon these allegations or indicate that it will forego pursuing them at trial.

In addition, the requested discovery is relevant to determining whether: (i) the Government views the type of patient outreach efforts BioScrip engaged in as "recommendations" such that they potentially could give rise to AKS liability, *see*, *e.g.*, Second Am. Compl. ¶ 7; and (ii) whether the specialty pharmacies' provision of information to patients (with respect to Exjade) and physicians (with respect to Myfortic) was promotional and sales-oriented, as the Government alleges, *see id.* ¶¶ 2, 5, 273, 284, or educational. The requested

[4] Indeed, the Government's contention that the nature of the information provided by specialty pharmacies to prescribing physicians is irrelevant in light of the Court's rulings on the motions to dismiss, *see*, *e.g.*, U.S. Opp. at 17, is belied by the Government's *own* discovery requests to the specialty pharmacies, served *after* the relevant decisions issued, seeking those communications. *See*, *e.g.*, Reply Decl. of Manisha Sheth, filed concurrently herewith, at Ex. CCC.

discovery similarly is relevant to issues of intent[5] and whether the statutory and regulatory framework provide sufficient notice that NPC's conduct violated the AKS, if it violates it at all.[6]

Finally, there is no merit to the Government's contention that NPC is engaged in a blind "fishing expedition." *See*, *e.g.*, U.S. Opp. at 12. NPC identified specific programs in its requests that, based upon its review of publicly available information, it believes are relevant to the allegations in this case, and the agencies it believes possess relevant information.[7] NPC seeks

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[5] Notably, the Government does not address NPC's argument, *see* Br. at 11, that the requested discovery is relevant to whether the alleged underlying violations of the AKS were knowing and willful, *see* 42 U.S.C. § 1320a-7b (prohibiting "knowing[] and willful[]" offer, payment, solicitation, or receipt of kickbacks), and focuses only on the *different* intent requirement for violating the FCA. Evidence that the Government itself viewed adherence initiatives as appropriate, and the scope of such sanctioned initiatives makes it more likely than not that NPC did not know that its conduct was wrongful. *See*, *e.g.*, *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996) ("willfulness" requires government to establish that defendant's conduct was *wrongful* (either because it had actual knowledge that its conduct violated the law or because its conduct was so "inevitably nefarious," "obviously evil," or "inherently bad" that "anyone consciously engaging in it has fair warning of a criminal violation").

[6] The Government's reliance upon *Visiting Nurse Association of Brooklyn v. Thompson*, 378 F. Supp. 2d 75 (E.D.N.Y. 2004) is unavailing. In that case, certain Medicare providers certified compliance with a cost-reporting regulation despite the fact that their claims contradicted the express terms of an official federal interpretation of that regulation. *See id.* at 95-97. Demonstrating "chutzpah of the highest order," the providers disregarded the interpretation, which they viewed as invalidly promulgated. *See id.* In this case, it is disputed (and entirely undecided) whether NPC's adherence efforts constitute promotion or marketing under existing OIG guidance, and whether NPC's rebates, discounts, and prescription allocations constituted "product conversion" programs or remuneration in exchange for performing "marketing tasks" as described in the 1994 HHS-OIG "Special Fraud Alert."

[7] The Government's extended discourse regarding the features of Medication Therapy Management ("MTM") plans required for Medicare Part D plans, *see* U.S. Opp. at 9-10, is a red herring. The program described in the text accompanying the footnote referring to MTM plans is the Star Ratings program for Medicare Advantage plans, administered by the Centers for Medicare and Medicaid Services, which provides financial incentives to Medicare Advantage plans that administer medical and pharmacy benefits in the form of "Quality Bonus Payments" for, among other things, ensuring that patients adhere to the medications prescribed to them.

this information because it has immediate relevance to allegations the Government continues to put at issue and the claims and defenses in this case.[8]

II. THE GOVERNMENT'S OBJECTIONS ARE UNSUPPORTED

A. The Government's Conclusory Claim Of Burden Lacks Merit

The Government makes no meaningful effort to support its burden objection. Its generalized claim of burden is insufficient to allow it to escape NPC's reasonable discovery requests. Unsubstantiated claims of burden are inadequate. *See*, *e.g.*, *Oleg Cassini, Inc. v. Electrolux Home Prods., Inc.*, No. 11 Civ. 1237 (AJN) (JCF), 2013 WL 466198, at *2 (S.D.N.Y. Feb. 7, 2013) (Francis, J.) ("'General and conclusory objections as to relevance, overbreadth, or burden are insufficient to exclude discovery of requested information.'"). "'Instead, the objecting party must show specifically how, despite the broad and liberal construction afforded the federal discovery rules, each request is not relevant or how each question is overly broad, burdensome or oppressive.'" *See*, *e.g.*, *id.*; *see also Blagman v. Apple, Inc.*, No. 12 Civ. 5453 (ALC) (JCF), 2014 WL 1285496, at *8 (S.D.N.Y. Mar. 31, 2014) (Francis, J.) ("[P]arties opposing discovery must supply specific evidence demonstrating the nature of the burden."). The decisions relied upon by the Government in defense of its burden objection are inapposite in that most of those cases involved patently overbroad requests for clearly non-relevant materials. *See Freedman v. Weatherford Int'l Ltd.*, No. 12 Civ. 2121 (LAK) (JCF), 2014 WL 3767034, at

[8] The cases cited by the Government for the proposition that NPC's discovery requests are speculative and lack a discernible link to the Government's claims are readily distinguishable. *See*, *e.g.*, *Surles v. Air France*, 00CIV5004 (RMBFM), 2001 WL 1142231 (S.D.N.Y. Sept. 27, 2001) (information regarding plaintiff's car loan and 401(k) beneficiaries not relevant to age and national origin discrimination claim or defense that plaintiff was fired for dishonesty); *Spina v. Our Lady of Mercy Med. Ctr.*, 97 CIV 4661 (RCC), 2001 WL 630481 (S.D.N.Y. June 7, 2001) (denying plaintiff's request in sexual harassment suit for discovery regarding harassment by employee who was terminated by defendant more than a year before plaintiff was employed by defendant, and noting strong policy reasons for doing so).

*3 (S.D.N.Y. July 25, 2014) (Francis, J.) (denying plaintiffs' request for collateral "discovery on discovery"), *reconsideration granted in part on other grounds by* 2014 WL 4097639 (S.D.N.Y. Aug. 14, 2014); *Viacom Int'l Inc. v. YouTube Inc.*, 253 F.R.D. 256, 262-63 (S.D.N.Y. 2008) (denying a request for production of database information concerning "the complete universe of videos available on YouTube").

What little the Government *does* say about the burden it would shoulder in complying with its discovery obligations is conclusory and not compelling, especially considering that—except for the States' inadequate agreement to produce documents only from their SSAs and only relating to Exjade,[9] *see* Br. at 10 n.5—the Government has made no effort to make suggestions for narrowing the substantive scope of NPC's requests or the relevant agencies to search to address its purported claims of burden. The U.S. in particular should not be heard to complain that "a wide range of federal agencies and healthcare facilities" would be required "to devote substantial time, personnel, and other resources to conduct searches based on nebulous concepts" given that it stood firm on its relevance objection and declined even to consider potential compromise limitations on scope.

Finally, not only does the Government fail to quantify the burden it would bear to comply with these discovery requests, its attempt to portray itself as having already shouldered significant discovery burdens is disingenuous. Although the U.S. boasts that it has "produced over 900,000 pages of documents to [NPC]," U.S. Opp. at 8, *see also id.* at 1, nearly 97% of the

[9] The States have failed to produce even these limited documents. In any event, the States' agreement is inadequate because limiting the requests to Exjade, a specialty medication, would exclude documents regarding issues that are not medication-specific, such as the structure and features of appropriate adherence initiatives, including whether refills are an appropriate metric to measure adherence. Similarly, limiting the requests to the Government's views of adherence programs conducted by government hospitals would exclude analyses conducted by state agencies of adherence programs operated by the private sector, which are equally relevant. *See id.* at 11.

approximately 907,000 pages the U.S. has produced to NPC were simply documents produced by third parties in response to subpoenas issued by the U.S. in the course of its pre-litigation investigation, or are transcripts of depositions. In stark comparison, to date NPC has produced to the Government nearly 25 million pages of NPC documents it had to collect, review, and produce in the first instance. The Government's unsubstantiated burden objection rings hollow.

B. The States Fail To Establish That They Lack Possession, Custody, Or Control Over Their Agencies' Documents

The States' argument that they are required to produce only documents from each State's respective SSA is flawed. First, the States argue that the SSAs, not the States themselves, are the real parties in interest because "it is each state's *Medicaid program* that has suffered damages." States' Opp. at 13. As an initial matter, the reach of party discovery is coterminous with the party's possession, custody, and control of information, not the locus of the damages. In any event, any recovery from the States' claims will flow directly to the States, not the SSAs, and it is the States, not the SSAs, that control this litigation. *See Edelman v. Jordan*, 415 U.S. 651, 663 (1974) ("[W]hen the action is in essence one for the recovery of money from the state, the state is the real, substantial party in interest[.]") (quotation marks and citations omitted); *Kansas v. Colorado*, 533 U.S. 1, 8-9 (2001) (holding that Kansas was real party in interest because "the record in this case plainly discloses that [it] has been in full control of this litigation since its inception. Its right to control the disposition of any recovery of damages is entirely unencumbered."). As real parties in interest to these suits and the named plaintiffs, the States bear the burden of responding to party discovery. *See JPMorgan Chase Bank v. Winnick*, 228 F.R.D. 505, 506-07 (S.D.N.Y. 2005) (holding that both real parties in interest and plaintiff had custody and control of documents); *Forstmann Leff Assocs. v. Am. Brands, Inc.*, No. 88 Civ. 4485 (JMC), 1991 WL 168002, at *4 (S.D.N.Y. Aug. 16, 1991) ("Discovery is favored where

the government is involved in the litigation in light of the obligation that every party has to be forthcoming with relevant information.").

The States devote several pages to describing the organization of various agencies under state law to argue that these entities' documents need not be produced because they are outside the possession, custody, or control of the States' Attorney Generals. *See* States' Opp. at 16-21. Not only do their cited authorities fail to support this proposition,[10] the relevant question is whether the documents are within the possession, custody, or control of the *States* or the SSAs, not the Attorneys General. *See* Br. at 14. The States are the parties; the Attorneys General are their counsel. The States fail to rebut NPC's showing that that the SSAs have possession, custody, or control over these entities' documents. *See* Br. at 13-16.

Even if the States' claim that *only* the SSAs are required to respond to discovery in actions brought by the States were correct,[11] NPC's motion to compel should nevertheless be granted because, as a condition to receiving federal funding for Medicaid, each of the SSAs must have "control" over third parties with whom they contract and sub-contract to provide Medicaid

[10] In several instances, the cited authorities simply provide that the Attorney General does not serve as counsel for the agency in question or that the agency has a board of regents. *See*, *e.g.*, States' Opp. at 16 (Regents of the University of California has separate counsel); *id.* at 16-17 (Illinois Attorney General does not have to represent University of Illinois); *id.* at 18 (University of Michigan has own legal counsel); *id.* at 18-20 (*one* state hospital is under the control of Rutgers University, which has separate counsel); *id.* at 21 (University of Washington governed by a board of regents). It is not clear why Indiana believes its Professional Licensing Agency or Board of Pharmacy are not under its control merely because they were created pursuant to statute, *see* Opp. at 17-18, and their websites (http://www.in.gov/pla/index.htm and http://www.in.gov/pla/pharmacy.htm) certainly suggest otherwise.

[11] *Boardman v. National Railroad Passenger Corp.*, 233 F.R.D. 259, 264 (N.D.N.Y. 2006), cited by the States, was brought by a specific agency, not the state itself, and, as the Court noted, "[t]he determination of control is often fact specific." *Id.* at 267. Even if *Boardman* applied to make the SSA, not the State, the "party" for purposes of party discovery, the SSAs have considerable control over the relevant state agencies. Thus, the States' speculation about whether private medical providers could be deemed under the control of the SSAs, *see* States' Opp. at 22-23, is misplaced. NPC is not seeking documents from private medical providers; it is seeking information under the control of the instrumentalities of the States (the named plaintiffs).

services. *E.g.*, Br. at 15-16; *Rosie D. v. Romney*, 256 F. Supp. 2d 115, 119 (D. Mass. 2003). Contrary to the States' suggestion, SSAs do not simply audit Medicaid participants, but administer all aspects of the program and have control over the relevant state agencies. *See* Br. at 14-16. *S.E.C. v. Tourre*, 10 Civ. 3229 (BSJ) (MHD), 2011 WL 350286 (S.D.N.Y. Jan. 31, 2011), cited by the States, in which the court denied a motion for an order "demanding that the SEC pursue documents held by a foreign private company and that it do so through the intervention of a foreign state and utilizing a mechanism that embodies an aspect of our Government's relationship with that foreign state," *id.* at *3, involved significant foreign relations concerns and has no relevance to this case. The States' objection should be overruled.[12]

CONCLUSION

For all of the foregoing reasons, NPC respectfully requests that the Court grant NPC's motion to compel in its entirety.

[12] The States complain that NPC served requests under state FOIA laws on various state entities seeking some of the same documents the States refused to provide in discovery. States' Opp. at 8. The States invited NPC to seek this discovery directly from these agencies by subpoena, *see* Sheth Decl. Ex. FF, so it is not clear why they are now criticizing NPC for seeking some of this information under the FOIA laws. NPC disclosed in its requests that it was seeking the documents for the purposes of this litigation and, in any event, NPC's rights under FOIA laws "are neither increased nor decreased" by reason of its status as a party to litigation. *Cf. Nat'l Labor Relations Bd. v. Sears, Roebuck & Co.*, 421 U.S. 132, 144 n.10 (1975).

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Respectfully submitted,

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